SYRACUSE UNIVERSITY
DEPARTMENT OF PSYCHOLOGY

CONSENT TO BE A RESEARCH SUBJECT

Brief Acceptance and Commitment Therapy for HIV-Infected At-Risk Drinkers

Pilot Randomized Clinical Trial

Background
This is a research study designed to try a new way of treating alcohol use among people living with HIV (PLWH). This study is being conducted by two faculty members in the Department of Psychology at Syracuse University: Dr. Sarah E. Woolf-King, PhD, MPH, Assistant Professor, and Dr. Stephen A. Maisto, PhD, Professor. I am a research assistant for this study and I will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to participate in this study because you have reported that you frequently consume alcohol, you are a person living with HIV, and you have expressed an interest in participating.

Why is this study being done?
We are conducting this research to gain knowledge about the feasibility and acceptability of a new treatment to help PLWH reduce their alcohol use increase their well-being. This study will help us to understand if the new treatment has potential to help PLWH. This study is being paid for by the National Institute of Health (NIH) in the United States.

How many people will take part in this study?
We expect approximately 75 people to take part in this part of the study.

What will happen if I take part in this research study?
If you agree to participate in the study, in addition to the activities described below, we will ask to remain in regular contact with you (i.e., weekly) via text messaging or email in order to check-in with you and remind you about study appointments.

1. **Baseline session (in person):** You will spend approximately 60-90 minutes with a research assistant who will help you complete a series of questionnaires, request that you complete a blood draw that will test for recent alcohol use, collect a small sample of hair that will be used to test for levels of HIV medications in your body, and be randomized to a treatment group. **You will be paid $60 for completing the baseline session.**

a. **Completion of self-report questionnaires.** The research assistant will ask you several questions about your current mental and physical health status. Your answers will be entered directly into a secure, computer-based survey.

b. **Collection of biological specimens.** Approximately five drops (approximately 1 cc) of blood will be obtained with a finger prick. The research assistant will puncture your fingertip with a microlancet to acquire the blood sample. You will not be told the results of the blood test for alcohol. The research assistant will also ask to cut several strands of hair from your head. These strands of hair will be used to test for levels of HIV medications that are currently in your body. You will not be told the results of the hair analysis.

c. **Randomization to two study groups.** You will be randomized into one of the two study groups that I will describe to you. Randomization means that you are assigned to a group by chance. A computer program will make this assignment. Neither you nor the research assistant can choose the group that you will be in

   i. **If you are randomized to group 1:** You will receive 5, 20-minute telephone-based sessions of an intervention designed to teach you mindfulness-based skills and strategies to manage your well-being and alcohol use.
   ii. **If you are randomized to group 2**: You will receive two, 20 minute, telephone-based treatment sessions and two, 5-10 minute check-ins, designed to discuss your current alcohol use and develop a plan for reducing this use.

2. **5 telephone-based treatment sessions.** Every week, for 5 consecutive weeks, we will ask you to engage in a telephone-based treatment that consists of a conversation with one of our research staff regarding your alcohol use. We will request to audio record your treatment sessions so that we can make sure your intervention is being delivered to you in a manner that is consistent with our treatment manuals. These recordings will be reviewed by the principal investigators (Dr. Woolf-King and Maisto). **You will be paid $5.00 for each successfully completed telephone-based treatment session.**

   i. **If you are randomized to group 1:** Each week, at a time of your choosing, a research assistant from the project will call you for a 20-minute session in which you will be asked to participate in a discussion about your alcohol use. Each week the content of the discussion will vary, and you will be provided with different activities and skills for managing your alcohol use and well-being. In the final session, you will be reminded about your follow-up appointments.

   ii. **If you are randomized to group 2**: Each week, at a time of your choosing, a research assistant from the project will call you for a brief discussion about your alcohol use. In week 1, the call will last approximately 20 minutes, in week 2 you will receive a 5-10 minute follow-up call to discuss your progress, in week 3 you will be asked to participate in another 20 minute discussion of your alcohol use, and in week 4 you will receive another 5-10 minute call to discuss your progress. In week 5 you will receive a final phone call to remind you about your follow-up appointment.

3. **6-week follow-up session (in person).** You will return for a study session after you have completed your treatment sessions. You will be asked to complete many of the same questionnaires you completed at the baseline session in addition to some questions about your experience with the treatment. You will also be

asked to complete another blood draw for alcohol biomarker testing and another hair collection for HIV medication testing. **You will be paid $60 for completing the 6-week follow-up session**

4. **3-month follow-up session (via telephone).** Three months after the baseline session a research assistant from the study will call you and ask you several questions about your physical and mental health. These questions will be many of the same questions you were asked in the baseline session. **We expect the call to take approximately 20-30 minutes and you will be paid $5.00 for your time.**

5. **6-month follow-up session (in person).** You will return for a final study session 6 months after your baseline appointment. You will be asked to complete the same questionnaires you completed at the 6-week follow-up session. You will also be asked to complete another blood draw for biomarker testing and another hair collection for HIV medication testing. **You will be paid $60 for completing the 6-month follow-up session**

Study location.
All of these procedures will be conducted in a private room in our lab space at 804 University Avenue, Syracuse, NY 13244. Telephone-based treatment sessions will take place in a location of your choice. We encourage you to find a private, quiet location that is convenient for you.

How long will I be in this study?
This study involves one baseline session, five telephone-based treatment sessions, and three follow-up sessions 6-weeks, 3-months, and 6-months after your baseline session. After you participate in the 6-month follow-up session, you will be finished with participating in this study.

Can I stop being in the study?
You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest (e.g., if answering study questions or engaging in the treatment sessions appears too distressing).

What side effects or risks can I expect from being in the study?
The most immediate risks associated with participation in the proposed research are: (1) loss of confidentiality, (2) emotional discomfort associated with answering sensitive questions about your physical and mental health and participating in a psychological treatment, and (3) mild physical discomfort from the finger prick.

1. **Loss of confidentiality**. There is the very slight but present chance of a breach of confidentiality inherent in any study that handles confidential data. Participation in the research will be contingent upon HIV+ status and admission of alcohol consumption, and due to the novel telephone-based treatment delivery, participants in the study may be identifiable to other community members. Loss of confidentiality may lead to unintentional disclosure of HIV status. Stigma associated with such disclosure may include social harms (e.g., breakup of couples following HIV detection), discrimination (e.g., a loss of employment or status in community), and psychological harm such as embarrassment. Finally, participants may disclose illegal drug use during the questionnaires administered in the study appointments which, if unintentionally disclosed, could result in discrimination, employment loss, psychological harms (e.g., stigma and shame), and legal consequences.

2. **Emotional discomfort** It is possible that participants may experience some emotional discomfort answering questions about sensitive, personal information (e.g., alcohol use, symptoms of anxiety and

depression) and engaging in activities associated with the treatment sessions. We expect this to be minimal. Participants assigned to group 1 will be asked to use mindfulness skills as a way of coping with uncomfortable emotions/thoughts/urges, which will require the experience, rather than avoidance, of these private experiences. This may produce a temporary increase in symptoms of anxiety (or other undesirable emotional states). This discomfort is expected to be transient and minimal. You may elect to discontinue any exercise you find too distressing and/or discontinue the intervention at any time without penalty

3. **Mild physical discomfort.** Participants will likely experience mild physical discomfort from the finger prick used to collect the dried blood spots (DBS). This discomfort is expected to be brief and minimal.

What steps will be taken to minimize these risks?
We will take the following steps to maintain the confidentiality of participant data:

1. **Use of Study Identification Numbers (IDs).** You will be assigned a unique study ID number that will be used on study forms. No identifying information will be associated with the questionnaires you complete, the information collected as part your telephone-based treatment sessions, or your blood and hair samples.

2. **Use of password protected and secure data storage.** All of the data we collect will be stored electronically on secure password protected servers. Only the PI and supervised, designated research staff will have access to the databases, and all your information will be stored according to your study ID.

3. **Management of tracking information with identifiable data.** We will ask you for some identifying information in order to be able to keep in touch with you during the study. All of this information (e.g., names, phone numbers) will be kept in a secure, password protected database and stored separately from your other study information (e.g., questionnaires).

4. **Use of a private room for telephone-based treatment sessions.** Study staff administering the telephone-based treatment sessions will be required to do so in a private interview room. We will also encourage you to find a private place to receive the treatment session, and will work with you to find a time and date so that you can engage in the treatment in a way the preserves your confidentiality.

5. **Storage of paper consent forms with identifiable data.** This informed consent form will be stored in a locked file cabinet in a locked room in our laboratory space. Only the PI and approved staff members will have access to the file cabinet.

6. **Storage of blood and hair samples.** Your blood and hair samples will be stored according to your study ID number and placed in a locked freezer or cabinet in our lab space to which only the PI and designated research staff will have access. When your samples are shared with the laboratory processing facility, they will not contain any identifying information.

7. **Handling of published data and reports.** No individual, identifying information will be including in any publication or presentation of the data collected for this project.

8. **You are free to refuse to answer any questions and/or discontinue study participation at any time without penalty**

Are there benefits to taking part in the study?
You may experience some psychological benefit (e.g., reduced alcohol use, reduced symptoms of stress and anxiety) and some benefit to your HIV-related management (e.g., increased adherence, lower viral load) from participation in the research study. In the long term, this research may also enhance the care of people living with HIV. The research team will give you referrals to counselors, clinics, or groups to address issues that arise about substance use or HIV.

What other choices do I have if I do not take part in this study?
You may choose to not participate at any time. If you choose to not participate, it will not affect your current healthcare.

Will information about me be kept private?
We will do our best to make sure that the personal information gathered for this study is kept private. We will store your audio-recorded treatment sessions by a number that is assigned to you at the beginning of the study. Your name will not be connected to your audio recordings or any other materials that you complete during your interview. Immediately after the completion of the interview, the recording will be uploaded to a secure, password protected server and stored according to an ID number and the electronic recorder will be erased immediately afterwards. Only the PI and designated research staff (e.g., the research assistant, a professional transcriptionist) will have access to these recordings, transcripts, and debriefs.

Your biological specimens will be stored for laboratory testing that will occur at a later date. Your sample will be stored according to a study ID number (not your name) and will be kept in a freezer or locked cabinet in a locked office. No identifying information will be shared with the laboratory processing facilities.

Your data will be destroyed 10 years after study completion. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. We will destroy information that could identify you such as your name, address, and phone numbers 10 years after the study has ended. We will store hard copies of materials (e.g., the informed consent) in locked offices and files. Electronic data will be stored on password protected servers and computers,

There are limits to confidentiality, however. We will keep your study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, as would be the case if we learn about your intent to harm yourself or others. Although it is very unlikely, if law enforcement officials ask to see data associated with the study, we would have to give it to them.

Will I be paid for taking part in this study?
You will receive the following compensation for study participation:

- Baseline appointment: $60
- Telephone-based treatment sessions: $5/session, up to a total of $25.
- 6-week in person follow-up appointment: $60
- 3-month telephone-based follow-up appointment: $5
- 6-month in person follow-up appointment: $60

If you decide to withdraw from participation from an appointment once we have started, you will be paid $10 for your time. If you decide to discontinue the study after you have begun your treatment sessions, you will receive all compensation for the sessions you have completed.

Compensation for study participation includes $10 to cover the cost of parking for two hours at a nearby parking garage (e.g., CNY Medical Center Garage).

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

Who can answer my questions about the study?
If you have questions about this research, you may contact Dr. Sarah Woolf-King (Tel: 315.443.9917). She is an Assistant Professor in the Department of Psychology at Syracuse University. If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please contact Syracuse University' s Institutional Review Board Office: T: 315.443.3013; Email: orip@syr.edu.

CONSENT

Permission To Contact For Follow-Up Research
We may conduct additional research on this important topic. May we contact you about participation in future studies? Indicating you are willing to be contacted does not obligate you to participate in any other study, nor does it affect your participation in this study.

☐ No, I prefer not to be contacted about future studies.
☐ Yes, I am willing to be contacted about future studies.

Phone:_____
Mailing Address _____

Consent To Participate In Research & Authorization To Use:
I am at least 18 years of age and hereby give my consent to participate in this research study. I agree that my personal information can be collected, used, and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form.

_____ _____
Signature of subject Date

_____
Name of subject

_____ _____
Signature of Person Obtaining Consent/Authorization Date

Syracuse University IRB Approved

_____ FEB 9 - 2019 JUN 6 - 2019

Name of Person Obtaining Consent/Authorization

Do you agree to have your interviews audio recorded (please check the box that applies)?

- ☐ Yes, I AGREE to have my interview recorded
- ☐ No, I DO NOT agree to have my interview recorded

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